DEC 2 3 2005

K052471

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant: HDC s.r.l
Via dell'Industria, 19
36030 – SARCEDO (Vicenza) - Italy
Tel: +39 0445 364148
Fax: +39 0445 383645

Contact Person:
Guido Bonapace
I.SE.NET.
Via Emilia, 418,
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Date Prepared: September 2, 2005

Device Name

Proprietary Name : HDC Spider Screw

Common/Usual Name: Bone Screw

Classification Names: Endosseous dental implant

Device Classification: Class II, 21 CFR 872.3640, Product Code DZE.

Predicate Devices:

510 K Number	Device Trade Name	Manufacturer
K042965	Tomas-pin	Dentaurum
K033767	Dual Top Anchor System	Jeil Medical
K041527	AARHUS Anchorage System	Medicon
K021584	Replace Scalloped Margin Implant System	Nobel Biocare

Device Description:

The HDC Spider Screws are titanium fixation devices to be inserted into the upper or lower jaws, designed to be immediately used (after the bone insertion) as fixation for orthodontic appliances. Spider Screws are provided in two configuration "Self Tapping" and "Self Drilling and Self Tapping." Self Tapping Spider Screws are manufactured from ASTM F67. Self Drilling and Self Tapping Spider Screws are manufactured from ASTM F136. The HDC Spider Screws are provided in two tip size diameters, 1.5 mm and 2.0 mm. These devices are provided non-sterile and must be sterilized prior to use.

Basis of Substantial Equivalence:

HDC Spider Screws are similiar to predicate devices in intended use, material, design, and function. The intended use is identical to K033767 and K041527. The design is substantially equivalent to K033767 and K041527.

Intended Use:

The HDC Spider Screw is a threaded titanium dental implant screw, intended to serve as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. The device is used temporarily and shall be removed after orthodontic treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2005

HDC S.R.L.
C/O Ms. Millie Lynn Bentley
Consultant
Alta Consulting
6512 Bannockburn Drive
Bethesda, Maryland 20817

Re: K052471
Trade/Device Name: HDC, Spider Screw
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: November 23, 2005
Received: November 25, 2005

Dear Ms. Bentley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

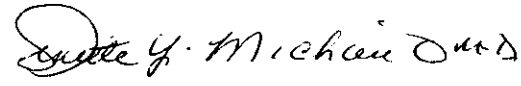
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K052471

Device Name: HDC, Spider Screw

Indications for Use:

The HDC Spider Screw is a threaded titanium dental implant screw, intended to serve as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. The device is used temporarily and shall be removed after orthodontic treatment.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kim Mulry for MSR

K052471